

K100475 #112

**510(k) Summary of Safety and Effectiveness:  
AxSOS® Locked Plating System Line Extension of 5mm Locking Inserts**

*Submission Information*

Name and Address of the Sponsor  
of the 510(k) Submission:

Howmedica Osteonics Corp  
325 Corporate Drive  
Mahwah, NJ 07430

APR 30 2010

For Information contact:

Melissa A. Matarese, Regulatory Affairs Associate  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430  
Phone: (201) 831-5116  
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Date Summary Prepared:

April 27, 2010

*Device Identification*

Proprietary Name:

AxSOS® Locked Plating System Line Extension of  
5mm Locking Inserts

Common Name:

Bone plates and screws

Classification Name and Reference:

Single/multiple component metallic bone fixation  
appliances and accessories, 21 CFR §888.3030  
Smooth or Threaded metallic bone fixation fastener,  
21 CFR §888.3040

Device Product Code:

87 HRS: Plate, Fixation, Bone  
87 HWC: Screw, Fixation, Bone

**Description:**

This Special 510(k) submission is intended to address modifications to the predicate Stryker Locking Inserts. The AxSOS® Locking Insert is being modified as part of a line extension of the AxSOS® Locked Plating System. The AxSOS® Locked Plating System contains 5mm Locking Inserts to which changes are being made to improve manufacturability. The modifications to the 5mm AxSOS® Locking Insert are to remove undefined free-form surfaces and replace them with clearly defined surfaces that mate with the plate hole geometry. The removal of these undefined free-form surfaces improves manufacturability, inspectability, and allows for a more precise fit into the plate holes. The changes are identical to the changes to the 4mm Locking Inserts cleared in K092419.

**Intended Use:**

The AxSOS® Locked Plating System Line Extension of 5mm Locking Insert modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject plates are provided below.

**Indications for Use:**

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The AxSOS® Locked Plating System of the Stryker Locked Plating System is intended for use in long bone fracture fixation. The AxSOS Locking Plates are indicated for fixation of long bone fractures including fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia and the distal femur.

**Statement of Technological Comparison:**

The following testing was conducted: Construct Torsion, Insertion Force, Cantilever Bending, Push-Out, and Construct Fatigue. The subject and predicate devices are made from Stainless Steel. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject AxSOS® System to the predicate device K050512.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Howmedica Osteonics Corporation  
% Ms. Melissa A. Matarese  
325 Corporate Drive  
Mahwah, New Jersey 07430

APR 30 2010

Re: K100475

Trade/Device Name: AxSOS® Locked Plating System Line Extension of 5mm Locking  
Insert

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and  
accessories

Regulatory Class: II

Product Code: HRS, HWC

Dated: March 31, 2010

Received: April 01, 2010

Dear Ms. Matarese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

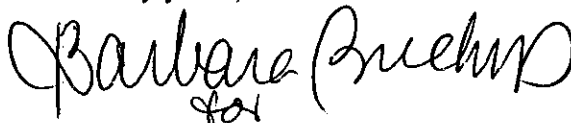
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Bruehner" with a small "for" written below it.

Mark N. Melkersen

Director

Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K100475

Device Name: AxSOS® Locked Plating System Line Extension of 5mm Locking Inserts

### Indications For Use:

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Prescription Use   X  

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use           

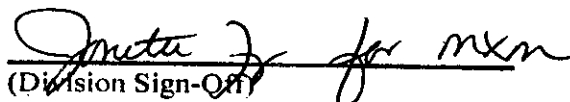
(21 CFR 807 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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